

REMARKS

All the claims currently in this application have been made subject to a restriction requirement and species election.

Turning first to the restriction requirement, applicants provisionally elect, for prosecution on the merits in this application, the invention denoted in the outstanding Official Action as Group I, encompassing Claims 1-20 and 24, drawn to nucleotides and a method of producing a polypeptide, classified in Class 536, subclass 23.5, for prosecution on the merits in this application. This election is made with traverse.

Applicants note that the Official Action avers that nine different patentably distinct inventions are embodied by the sixty-nine claims of the present application. However, the Official Action admits that none of the criteria for patentable distinctiveness, as set forth at MPEP §806.05, which includes nine separate subsections, apply to the claims of this application subject to the instant restriction requirement. In the absence of such a citation, applicants respectfully submit that the restriction requirement of record is improper.

Although the Official Action admits that no specific subsection of MPEP §806.05 supports patentable distinctiveness among the alleged nine separate inventions embodied in the claims of the present application, the Official Action then proceeds to make further allegations in support of patent distinctiveness.

It is unnecessary for applicants to specifically traverse each of these arguments supporting patentable distinctiveness. Suffice it to say, the failure of the Official Action to connect any of these grounds to any of the nine subsections of MPEP §806.05, which provide grounds of patentable distinctiveness of related inventions, conclusively establishes that none of the grounds advanced in the outstanding Official Action meet the requirements for

imposition of a restriction requirement. Indeed, applicants submit that the allegations made in support of patentable distinctiveness, without foundation from any specific section of MPEP §806.05, are based on allegations and presumptions not supported by any applied reference.

It is noted that the only MPEP section specifically relied upon to establish patent distinctiveness is MPEP §806.04(b). That section is relied up to support the alleged distinctiveness between the invention of the claims of Group I and Group VIII. The third paragraph of that section holds that patent distinctiveness is proven if it can be shown that species which may be related to each other as intermediate and final product are distinct if the intermediate product is useful other than to make the final product.

The Official Action argues that the transgenic animal of Claims 45 and 46, the invention of Group VIII, is the final product of the intermediate isolated nucleic acid, the invention of Group I, which the Official Action argues can be used as a probe for diagnostic purposes. The Official Action, however, provides no support for this utility. In the absence of such other use, unrelated to the utility of the isolated nucleic acid set forth in the present application, this assumption cannot be sustained.

The second alleged utility of the intermediate product of the claims of Group I, to produce the polypeptide of Claims 21, 22 and 25, which constitutes Group II, is unsustainable. This is so insofar as if this was the case it would be proper to apply MPEP §806.05(h), e.g. the product of the Group I nucleic acid in a process using that nucleic acid in making the polypeptide of Group II. The absence of this ground is a tacit admission that the basis of this ground of patent distinctiveness is groundless.

The above remarks, which establish that the Official Action assertion of the patent distinctiveness between the nine set of claims is not met, is buttressed by a second basis for

removal of the provisional restriction requirement of record. That is, the statute, 35 U.S.C. §112, in its first sentence states:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. (Emphasis added)

Pursuant to this statutory dictate, the implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct. 37 C.F.R. §§1.141 - 1.142. Without both independence and distinctiveness, a restriction requirement is not authorized.

In the present application the nine sets of claims, which the Official Action has grouped separately, are not independent of each other so as to justify a restriction requirement. The claims of Invention I, Claims 1-20 and 24, are drawn to polynucleotides and methods of producing a polypeptide. These claims cannot be considered "independent" of the claims of Inventions II to VIII. Rather, these nine sets of claims are interrelated and interdependent.

The interdependence of the nine allegedly independent sets of claims, set forth in the Official Action, is confirmed -- indeed it is mandated -- by virtue of the fact that the descriptive requirements of 35 C.F.R. §112 compel disclosure of all aspects of the nine allegedly distinct and independent inventions of the present application. An application claiming polynucleotides and methods of producing polypeptides must, of necessity, also describe the polypeptides and their properties, which are set forth in the specification in support of the other claims of this application. Consequently, it is clear that all aspects of the present invention, including the nucleic acid of Invention I, as well as the claims of Inventions II to VIII, are necessarily interdependent, not independent of each other. Thus, the above

remarks provide yet further support for the proposition that the requirement for restriction in the present application is misplaced.

Applicants note that the instant restriction is supported by reference to different classes and subclasses of the Patent and Trademark Office classification system in which the six groups of claims are classified. The inference that the classification of claims support a restriction requirement is submitted to be improper.

Reliance on a supposed classification of groups of claims does not establish independence and distinctiveness. The classification system has no statutory recognition with regard to whether inventions are independent and distinct. The sole purpose of the classification system is as an aid in identifying and searching for patents directed to the same general inventive entity.

The classification system is also an unreliable basis for requiring restriction between claims to various aspects of applicants' unitary invention because the Patent and Trademark Office classification system exhibits considerable overlap of technical definitions. In particular, the definition of classes and subclasses in the classification system does not prevent rejection of claims found in patent references classified in other classes or subclasses.

Furthermore, the classification system is a poor basis for restriction between related aspects of an invention insofar as classification definitions change over time. Thus, a classification that may have seemed to support restriction at a given time can change, thereby casting a shadow over the propriety of a restriction requirement later during the term of patents issued from parent and divisional applications. Indeed, classifications change in response to consideration of administrative convenience, often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have

nothing to do with whether the subject matter of patents assigned to different classifications are “independent and distinct,” as those terms are used in 35 C.F.R. §121, which fact proves that basing restriction requirements on the classification system is improper.

It is emphasized that the restriction requirement of record is not mandatory and is indeed contrary to the public interest. Courts have recognized that it is in the public interest to permit an applicant to claim all aspects of an invention in a single application, as applicants have done herein. The CCPA has observed:

We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe, in a manner required by 35 U.S.C. §112, all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. In re Kuehl, 456 F.2d 658, 666, 117 USPQ 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed description supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application directed to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase in official fees and the resultant potential limitation of an applicant’s financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose of promoting and encouraging the progress of science and the useful arts.

It is vital that restriction requirements issue with proper statutory authorization because patents issuing on divisional applications, which are filed to prosecute claims that are held to be distinct and independent, can be vulnerable to legal challenge predicated upon the allegation of double patenting.

The third sentence of 35 U.S.C. §121, which states that a patent issuing on a patent application “shall not be used as a reference” against the divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same invention double patenting. Studiengesellschaft Kohle mvP v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 USPQ 837, 840 (Fed. Cir. 1986).

The same Court in Gerber Garment Technologies Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990) held that § 121 does not insulate a patentee from an allegation of “obviousness-type” double patenting and, in fact, the invalidation, on double patenting grounds, of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a Terminal Disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on a divisional application.

Although applicants have met the requirement that they elect the claims of one of the alleged inventions for prosecution on the merits, i.e. Invention I, applicants submit that the above remarks establish the unitary nature of the claims of the present application which have been made subject to restriction. Reconsideration and removal of the provisional restriction requirement of record is thus deemed appropriate. Such action is respectfully urged.

A species election has also been imposed in the present application. Specifically the Official Action submits that there are four patentably distinct species claimed in the present application.

It is noted in passing that the third recited species SEQ ID NO: 2, to which the claims of the present application have been restricted in the event that a generic claim is not found

which encompasses the other species, has been incorrectly identified in the outstanding Official Action. That is, the Official Action indicates that one of the species is polypeptides of SEQ ID NO: 2. A review of the specification makes clear that the species intended to be recited encompassing SEQ ID NO: 2 is a nucleotide sequence of the canine MC4R, rather than a polypeptide sequence. The polypeptide sequence of the canine MC4R is SEQ ID NO: 4.

Applicants traverse the species election imposed in the outstanding Official Action. Attention is directed to MPEP §806.04(a). Therein it is recited that the enabling statute permitting restriction requirements, 35 U.S.C. §121, provides that a reasonable number of species may be claimed in one application. The Official Action alleges that four patentably distinct species are embodied by the claims of the present application. Even if the Official Action were correct in arguing that the subject species are patentably distinct, still four is a reasonable number of species so that all of them should be examined in the present application.

It is furthermore noted that species are usually independent. MPEP §806.04(b). As such, the above remarks, establishing that a restriction requirement is proper only when claims are directed to both distinct and independent inventions, applies to this point. Any restriction predicated upon allegedly distinct species does not provide the proper predicate for the imposition of a restriction requirement that requires that the restricted out claims be patentably independent.

Reconsideration and removal of the species election is therefore respectfully solicited.

The above remarks establish the unitary nature of all the claims of the present application. Reconsideration and removal of the provisional restriction requirement and

species election followed by prompt examination and allowance of all the claims currently in this application, Claims 1-69, is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, reading "Marvin Bressler". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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